II. REMARKS

Claims 1 to 20 are pending in the subject application. Claims 1-4, 6-14, and 16-20 have been withdrawn from examination. Claim 5 has been amended. Support for the amendment to claim 5 is found in the specification on page 3, line 23 to page 4, line 2; page 12, lines 20 to 22; and page 19, line 1 through page 22, line 32. An issue of new matter is not raised by this amendment and entry thereof is respectfully requested.

In view of the preceding amendments and the following remarks, reconsideration and withdrawal of the rejections of claims 5 and 15 is respectfully requested.

35 U.S.C. §102

Claim 5 stands rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Erding et al. [EP 0 879 881 A1]. The Office alleged that Erding et al. anticipates because it teaches delivery of a therapeutically effective amount of a polypeptide having substantially (99.5%) sequence identity to Applicants' Seq. ID No. 2 for the treatment of diseases. The Office alleged that therefore, administration of the polypeptide would inherently reduce phosphate re-absorption as recited in claim 5.

Claim 5 also stands rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Lark et al. [EP 0 887 406 A2]. The Office alleged that Lark et al. anticipates because it teaches delivery of a therapeutically effective amount of a polypeptide having substantially (99.3%) sequence identity to Applicants' Seq. ID No. 2 for the treatment of diseases. The Office alleged that therefore, administration of the polypeptide would inherently reduce phosphate re-absorption as recited in claim 5.

Applicants respectfully traverse. Erding et al. discloses the administration of a polypeptide for the treatment of "abnormal conditions such as, heart disease, hypertension, cardiovascular diseases, kidney diseases, obesity, insulin resistance, diabetes, CNS diseases, additions., related to both an excess of and insufficient amounts of ATG-1639 polypeptide

activity." (Erding et al. p. 11, lines 51 to 53). Lark et al. discloses the use of a protein for the treatment of a laundry list of diseases from chronic and acute inflammation to restenosis and brain injury. Neither Erding et al. nor Lark et al. makes mention of phosphate re-absorption and how to treat conditions related to dysregulation of phosphate re-absorption. Neither reference discloses the relationship between the expression level of the protein and phosphate metabolism. Neither Erding et al. nor Lark et al. teach how one can modulate phosphate re-absorption by administration of a protein having the same or similar sequence to that identified by Applicants as mammalian frizzled-related protein-4. Accordingly, the references do not anticipate, explicitly or inherently, because each fails to disclose or enable the claimed method. *See, e.g., Elan Pharm. Inc. v. Mayo Foundation*, 346 F.3d 1051 (Fed. Cir. 2003). (To serve as an anticipating reference, the reference must enable that which it is asserted to anticipate. Enablement requires that the prior art reference teach one of skill in the art to make or carry out the claimed invention without undue experimentation.)

Additionally, there is no disclosure in the cited references, explicit or inherent, of treating a subject in need of treatment of a disease or condition related to phosphate re-absorption. Thus because the subjects to which the drug is administered is different from that claimed in claim 5, the references do not inherently disclose the invention of claim 5.

For these reasons, the rejections are improper and reconsideration and withdrawal of the rejections under 35 U.S.C. § 102 is respectfully requested.

Applicants also respectfully disagree with the Office's statement that the "instant claims and Erding et al. provide the same level of guidance and therefore are enabled to the same extent." (Statement appearing in last paragraph of page 4 of Office Action.) A similar comment was made by the Office on page 5 of the Office Action concerning the Lark et al. reference.

Erding et al. enabled the sequence of the protein and its expression in various expression systems, *e.g., E. coli*, baculovirus and mammalian. Erding et al. also teaches how one may determine tissue distribution of the protein, but does not provide any statements regarding tissue distribution of the protein. Lark et al. also enabled the sequence of the protein, but not its expression in various expression systems. However, Lark et al. conducted Northern blot analysis

and determined that the protein was expressed at high levels in ovary, testes and spleen and at moderate levels in prostate, small intestine, colon, skeletal muscle, and heart. Lark also noted that it was expressed at much lower levels in thymus, placenta, lung, kidney and pancreas.

In contrast, Applicants have shown on pages 44 and 46 of the application that the protein used in the claimed methods is involved in phosphate re-absorption. Thus, contrary to the Office's assertion, the Applicants' claimed methods are enabled to an extent beyond that shown in the cited references.

Objection to Claim 15

Claim 15 was objected to on the ground that it is dependent on a rejected base claim. Upon removal of the rejections of claim 5, claim 15 will also be in condition for allowance.

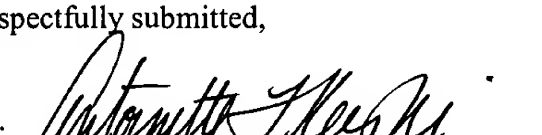
III. CONCLUSION

No additional fee, other than the fee for a one month extension of time, is deemed necessary in connection with the filing of this Response. However, if the Patent Office determines that an extension and/or other relief is required, Applicants petition for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 50-2518**, referencing billing number **7009072002**. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Should a telephone advance prosecution of the subject application, the Examiner is invited to contact the undersigned at (650) 849-4950.

Respectfully submitted,

Date: January 22, 2004

By: 

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